

II. Remarks

A. Status of the Claims

Claims 1-8 and 11-20 will be pending after entry of this amendment. Claims 9-10 and 21-36 were previously canceled. Claims 1, 2, 12, 15, 16, and 18-20 have been amended without prejudice. Support for amendments to claims 1, 2, 12, 15, 16, and 18-20 can be found throughout the application as originally filed, e.g. in the original claims and U.S. Patent No. 6,087,163, incorporated by reference at page 13, lines 12-15 of the present specification. Applicant submits that no new matter has been added by virtue of this amendment.

Prior to addressing the current rejections, Applicant wishes to thank the Examiner for removing the rejection of claims 1-8 and 11-20 under 35 U.S.C. §112, second paragraph for being indefinite for peptide identity in light of Applicant's amendment of the claims.

B. Claim Rejections Under 35 U.S.C. §112, first paragraph

In the Office Action, claims 17-20 were rejected under 35 U.S.C. §112, first paragraph, for scope of enablement for diagnostic methods utilizing polypeptides. Specifically, the Examiner stated that while the '163 patent (incorporated by reference in its entirety into the instant application) "does teach immunoassays in general, it does not teach the specific sequences in the instant claims." The Examiner thus maintained the rejection because the "instant specification teaches computer-generated sequences of *M. tuberculosis* DNA with predicted proteins, but does not teach that the claimed sequences can diagnose infection with *M. tuberculosis*."

This rejection is respectfully traversed. Applicants respectfully submit that the instant application enables one of skill in the art to make and use the presently claimed invention, i.e. an isolated DNA molecule or a polypeptide having the specific recited sequences. Specifically, Applicants submit that the instant application:

- (1) teaches the specific sequences of the instant claims (Figures 1 and 2);
- (2) identifies such sequences as encoding for secreted polypeptides (page 10, lines 19-21);
- (3) teaches that proteins that are actively secreted by bacteria are effective as antigens that are capable of inducing protective immunity to an organism (page 10, lines 12-16); and

(4) teaches working examples of serologic immunoassays used to detect immune response to polypeptides of *M. tuberculosis* (U.S. Patent No. 6,087,163, incorporated by reference at page 13, lines 12-15 of the present specification).

Accordingly, Applicants submit that the disclosure of the instant application would enable one skilled in the art to make and use the invention in accordance with the present claims.

In making the rejection, the Examiner further stated that the term "segments" is not enabled because "the instant specification does not provide any working examples of the complete polypeptides, nor does it teach if any of the segments would retain the required activity."

This rejection is respectfully traversed. Applicants submit that where a whole polypeptide has been identified as likely to produce a desired antigenic response, it would not constitute undue experimentation to further identify segments of that polypeptide which are also likely produce the desired antigenic response. The Examiner is reminded that "[t]he mere fact that the experimentation may [be] difficult and time consuming does not mandate a conclusion that such experimentation would [be] considered to be 'undue' in this art. Indeed, great expenditures of time and effort [are] ordinary in the field of vaccine preparation." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006) (citing the Board of Patent Appeals and Interferences and concluding that it did not err in its conclusion of enablement), and "[a] patent need not teach, and preferably omits, what is well known in the art." MPEP §2164.01. Thus, only enough detail must be included in the specification to enable a person of skill in the art to make and use the invention without undue experimentation. *Falko-Gunter* at 1366. In the present case, Applicants have identified a small number of polypeptide sequences that are likely to produce a desired antigenic response. Applicants submit that the teachings of the instant specification, coupled with the knowledge of one of skill in the art, would enable one to make and use the claimed invention without undue experimentation, and that such a person would have a reasonable expectation of success in such an endeavor.

Accordingly, Applicants respectfully submit that the rejection of claims 17-20 under 35 U.S.C. §112, first paragraph, be removed.

C. Claim Rejections Under 35 U.S.C. §102(b)

1. Claim 1

In the Office Action, claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Walker et al., U.S. Patent No. 5,736,365. Specifically, the Examiner stated that because Walker et al. utilizes the whole DNA genome of *M. tuberculosis* as a starting material for probes and primers of assays, it also teaches the isolated DNA as recited by claim 1.

In response, Applicants have amended claim 1 by replacing "comprising" with "consisting." Applicants submit that Walker et al. does not teach an isolated DNA molecule consisting of a DNA sequence encoding a polypeptide with an amino acid sequence selected from the group recited in claim 1. Accordingly, Applicants respectfully submit that the rejection of claim 1 under 35 U.S.C. §102(b) be removed.

2. Claim 11

In the Office Action, claim 11 was rejected under 35 U.S.C. §102(b) as being anticipated by Horwitz et al., U.S. Patent No. 5,108,745. Specifically, the Examiner stated that because Horwitz et al. teaches the isolation of *M. tuberculosis* secretory polypeptides, it also teaches the sequences the isolated polypeptide of claim 11.

This rejection is respectfully traversed. A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987). Claim 11 recites (1) a polypeptide that (2) is isolated and (3) has an amino acid sequence selected from a group of six enumerated sequences. Applicants submit that Horwitz et al. does not teach each and every one of these elements. Thus, Applicants respectfully submit that the rejection of claim 11 under 35 U.S.C. §102(b) be removed.

D. Rejections Under 35 U.S.C. §112, second paragraph

In the Office Action, claims 2, 4, 6, 8, 12, 14, 15, 16, 18, 19, and 20 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 2, 12, 15, 16, 18, 19, and 20

The Examiner stated that with respect to claims 2, 12, 15, 16, 18, 19, and 20, it is unclear what is and what is not considered a "specific" antigenic property.

In response, Applicants have amended the claims to include the term "*Mycobacterium tuberculosis*" before the term "specific" to indicate that the segments are capable of eliciting an antigenic response to *Mycobacterium tuberculosis*. Therefore, Applicants respectfully submit that the rejection of claims 2, 12, 15, 16, 18, 19, and 20 under 35 U.S.C. §112, second paragraph, be removed.

2. Claims 2-8 and 12-16

The Examiner stated that claims 2-8 and 12-16 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention insofar as they depend from rejected claim 1 and claim 11, respectively. In view of the amendments made to claims 1 and 11, and the arguments presented *supra*, Applicants respectfully submit that the rejections to independent claims 1 and 11 have been addressed and therefore request that the current rejection of claims 2-8 and 12-16 under 35 U.S.C. §112, second paragraph, be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973) 422-6532. The undersigned may also be contacted by e-mail at lschroeder@lowenstein.com. All correspondence should be directed to the address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Direct Account 50-1358.

Respectfully submitted,
Lowenstein Sandler PC

A handwritten signature in black ink, appearing to read 'Lisa K. Schroeder', written over a horizontal line.

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